Complete Summary

GUIDELINE TITLE

Bacterial vaginosis. In: Sexually transmitted infections: UK national screening and testing guidelines.

BIBLIOGRAPHIC SOURCE(S)

Keane F, Ison C, Noble H, Estcourt C. Bacterial vaginosis. In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 40-6. [29 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bacterial vaginosis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases

Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide advice on what tests for bacterial vaginosis are most appropriate in a United Kingdom genitourinary (GU) clinic setting (excluding human immunodeficiency virus [HIV]-infected patients)
- To provide a basis for audit
- To support clinics when bidding for additional resources to meet national standards

TARGET POPULATION

Women in the United Kingdom with or at risk for bacterial vaginosis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Diagnostic tests:
    - Amsel's Criteria
    - Appearance of Gram-stained smear according to modified Ison-Hay scoring system
2. Screening of defined patients groups
3. Testing of vaginal wall smears (posterior vaginal wall sample-blind in pre-pubertal women and those declining speculum examination)

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A Medline search was conducted from 1966-January 2005 using the terms bacterial vaginosis, diagnostics, pregnancy, screening and treatment as key words. A Medline search was also conducted 1988- December 2004 using bacterial vaginosis, pelvic inflammatory disease and treatment. The Cochrane data base was also searched using the terms bacterial vaginosis, diagnosis and pregnancy. The Centres for Disease Control and Prevention guidelines for bacterial vaginosis and the draft revised guidelines for the management of bacterial vaginosis were also consulted.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed following the methodological framework of the Appraisal of Guidelines Research and Evaluation instrument (AGREE - adapted as described in *Int J STD and AIDS* 2004 15:297-305).

The extent to which the guideline represents the views of intended users has been addressed primarily by the authorship coming from the multidisciplinary membership of the Bacterial Special Interest Group (BSIG). As practising clinicians the authors were able to draw on their experience of applying the tests to symptomatic and asymptomatic patients, but it was not feasible to obtain formal input from representative patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

A. Evidence at level Ia or Ib
B. Evidence at level IIa, IIb, or III
C. Evidence at level IV

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After drafting, other health care professionals and professional bodies in genitourinary (GU) medicine were asked to comment, the draft guidelines posted on the British Association for Sexual Health and HIV (BASHH) website for 3 months, and all comments reviewed before final publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence (**I-IV**) and grade of recommendation (**A-C**) are provided at the end of the "Major Recommendations" field.

Recommended Tests

A variety of tests, which reflect the changes in vaginal ecology, have been used to diagnose bacterial vaginosis (BV). Isolation of the bacteria associated with this

condition, such as *G. vaginalis*, has a poor specificity (these bacteria being present in a proportion of normal women, albeit in smaller numbers) and is discouraged. Other tests that detect the biochemical changes associated with BV are more useful for studies on pathogenesis rather than for clinical diagnosis and include the detection of sialidase and proline aminopeptidase. Two diagnostic methods for BV have been used extensively in genitourinary medicine clinics and remain the tests of choice. Both require interpretation within the given clinical scenario.

1. **Amsel's Criteria**

   The presence of three or more of the composite criteria is considered consistent with BV, and this has been used as the gold standard for many years.

   - Typical appearance of discharge at vaginal examination
   - Vaginal discharge pH > 4.5
   - Positive 'whiff test' following the addition of potassium hydroxide to a sample of discharge
   - Clue-cells on dark-ground microscopy of a saline wet mount preparation

   The criteria are simple to perform, particularly in a clinic setting and require minimal material with the exception of a microscope. However, the disadvantages are that the patient must undergo a vaginal examination and the recognition of the vaginal discharge and the fishy 'smell' has a subjective endpoint. In the majority of United Kingdom (UK) clinics the 'whiff' test is no longer performed because of the caustic nature of the potassium hydroxide, hence invalidating the method, which is dependent on measurement of all four criteria to achieve a high sensitivity for the diagnosis of BV.

2. **Appearance of Gram-Stained Vaginal Smear**

   The grading or scoring of Gram-stained smears offers an alternative to use of the composite criteria; it has the advantage of a more objective endpoint, and allows for a common approach that can be audited. A microscope is required. The original method divided patients into two groups, with or without BV (normal), but subsequent methods have included an intermediate category, believed to be a transition between normal and BV. The disadvantage is that multiple methods have been described and are in use resulting in a lack of consistency in diagnosis and reporting. One method which is widely used particularly for research studies requires counting of bacteria; this is time consuming and not feasible in a busy genitourinary medicine (GUM) clinic. A number of simplified schemes have been described but the grading of vaginal flora described by Ison and Hay allows a method of assessment that gives a good correlation with Amsel's criteria for the diagnosis of BV and correlates well with other scoring methods. This latter method has been endorsed by the Bacterial Special Interest Group of the British Association for Sexual Health and HIV (BASHH).

Recommended Diagnostic Test: Appearance of Gram-Stained Smear According to Modified Ison-Hay Scoring System

Modified Ison-Hay suggests five grades of flora:

Grade 0 - Epithelial cells with no bacteria

Grade 1 - Normal vaginal flora (*lactobacillus* morphotypes alone)

Grade II - Reduced numbers of *lactobacillus* morphotypes with a mixed bacterial flora

Grade III - Mixed bacterial flora only, few or absent lactobacillus morphotypes

Grade IV - Gram positive cocci only

Grades 0, I and IV are found in women without BV

Grade II is intermediate and not found in women with BV as defined by Amsel's criteria.

Grade III is consistent with BV as diagnosed by Amsel's criteria.

Thus, only Grade III flora is indicative of BV. There is some evidence to suggest that Grade II flora responds to oral, but not vaginal clindamycin in pregnant women. There is insufficient evidence on the clinical significance of grades 0, II and IV in the non-pregnant population and their response to standard treatment regimens for BV.

Diagnostic Methods for BV

	Amsel' s Criteria	**Gram-Stain Ison/Hay**
Convenient to Perform	Yes	Yes
Microscope Required	Yes	Yes
Caustic Material Required	Yes	No
Reproducible	No	Yes

Screening Should Take Place in the Following Patient Groups

- Women presenting with vaginal discharge, an offensive odour or any genital symptom. (**Evidence Level Ia; Grade of Recommendation A**)
- Women found to have a copious discharge at examination. (**Grade of Recommendation A**)
- Pregnant women with a history of previous pre-term labour may be offered screening. (**Evidence Level Ia; Grade of Recommendation A**)
- To date there is insufficient evidence to support routine screening of asymptomatic pregnant women. (**Evidence Level Ia; Grade of Recommendation A**)
- There is some evidence to support screening and treating BV prior to termination of pregnancy to reduce subsequent endometritis and pelvic

inflammatory disease (PID) (**Evidence Level Ib; Grade of Recommendation B**)
- There is a complete lack of evidence to inform any decision on screening asymptomatic non-pregnant women as regards PID outcomes. (**Evidence Level IV; Grade of Recommendation C**)

Sites for Testing

Vaginal wall smear following the insertion of a speculum is recommended.

Pre-pubertal women and those declining speculum examination

- Posterior vaginal wall sample -blind

Pregnant women

- Vaginal wall smear

Sex workers

- No different advice

Men

- Not applicable

Recommendation for Test of Cure

There is no available evidence to support or refute need for a test of cure. (**Evidence Level IV; Grade of Recommendation C**)

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

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IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grading of Recommendations

A. Evidence at level Ia or Ib
B. Evidence at level IIa, IIb, or III
C. Evidence at level IV

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis of bacterial vaginosis (BV)

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Screening Guidelines Steering Committee
Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Dr Frances Keane, Department of Genito-urinary Medicine, Royal Cornwall Hospital, Truro; Professor Cathy Ison, Health Protection Agency, Colindale, London; Dr Heather Noble, Ambrose King Centre, Barts and the London NHS Trust, London; Dr Claudia Estcourt, Ambrose King Centre, Barts and the London NHS Trust

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Frances Keane, Cathy Ison, Heather Noble, and Claudia Estcourt have no conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from British Association for Sexual Health and HIV Web Site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Specifications for the development of UK guidelines on the management of sexually transmitted infections (STIs) and closely related conditions 2005. London (UK): British Association of Sexual Health and HIV (BASHH); 2005. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the British Association for Sexual Health and HIV Web site.

Additionally, auditable outcome measures can be found in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 20, 2008. The information was verified by the guideline developer on October 20, 2008.

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